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| EXAMINER | |
|---|---|
| KISHORE, GOLLAMUDI S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/024,504 | ORTHOEFER, FRAND T. | |
| | Examiner | Art Unit | |
| | Gollamudi S Kishore, PhD | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *24-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-23 in Paper dated 1-20-2004 is acknowledged. The traversal is on the ground(s) that art relevant to the patentability of a solid liquid crystal phospholipid composition and a process of making the same, might very logically be found in the same art classes. This is not found persuasive because as set forth in the restriction, the composition containing phospholipids is classified in class 514 and patents falling in this class do not necessarily disclose the process of making them. Furthermore, the examiner is required to make one-way distinctiveness between the groups and this has been done so by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 recites names such as Meglac, Super-Lac and others. Instant specification does not provide guidance as to what they are.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from claim 1 how the lecithin is modified. How can one determine how lecithin is modified by just reciting a formula of the compound? The modification made should be recited in the claim.

'said lecithin' in claim 2 and 'lecithin phospholipid' in claim 3 lacks an antecedent basis in claim 1. What is recited in claim 1 is 'modified lecithin'.

'phosphatidylcholine' another name for 'lecithin'. Yet claim 4 recites this compound as in addition.

It is unclear as to what applicant intends to convey by lecithin in the form of a liquid, coated, uncoated as recited in claim 8. Lecithin exists as a solid form. It is unclear how it is liquefied. Also unclear is what applicant intends to convey by 'uncoated' and 'coated' and 'enriched', or 'bleached' or 'unbleached'. As pointed out above, lecithin is phosphatidylcholine how can this be bleached or unbleached or enriched?

The distinction between 'fats' and 'rumen inert fats' in claim 9 is unclear. Similar is the case with fatty acid soaps and fatty acid salts. Soaps are fatty acids salts.

What is being conveyed by 'disintegrants' recited as active agent in claim 9?

'other animal medicaments' is not a positive recitation.

Claim 18 recites metals; if applicant's intent is to convey that these metal ions in combination of a fatty acid, then the examiner suggests restructuring the claim.

The distinction between these salts of these fatty acids in claim 18 and calcium salts of long chain fatty acids recited as inert fats in claim 19 is unclear.

It is unclear as to what 'Megalac' and others recited in claim 20 represent. The examiner suggests reciting the chemical names.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-6, 8-19 and 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,312,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to a specific

modified lecithin pharmaceutical composition and instant compositions reciting generic 'modified lecithin' thus, encompass the patented compositions.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 8-9, 11-12, 15-16, 18 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 354 442.

EP teaches lecithin tablets containing soy lecithin, a mixture of sorbitol and mannitol (palatinit) vitamins and minerals. Some compositions also contain Magnesium stearate (note abstract, Examples 30-33 and Tables I and II and claim 6). Magnesium is a multivalent cation. The intended use has no significance in composition claims. Since instant claims do not recite how lecithin is modified, it is deemed that lecithin which is modified by mixing with platinit meets the requirements of instant claims.

10. Claims 1-6, 8-9, 11-12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Curatolo (5,108,756).

Curatalo discloses liquid crystals lecithin for the delivery of drugs. The drugs include antibiotics, electrolytes, vitamins and others. The compositions also include salts of fatty acids and sugars such as sucrose and disintigrants such as silica. The

amount of active agent is at least 5 %. The formulations are in the form of tablets or capsules and are either coated or uncoated (note the abstract, columns 4-8, Examples and claims). As pointed out above, the intended use has no significance in composition claims.

11. Claims 1-4, 6-11, 13-14, 16, 18-19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda (5,227,166).

Ueda teaches feed additive compositions for ruminants containing lecithin and an active agent such as amino acids (lysine, methionine), carbohydrates such as starch (disintegrant) and glucose, vitamins, antibiotics (tetracycline) and choline. The compositions further include, inorganic calcium and magnesium salts, salts of fatty acids. The compositions are coated (columns 3-4, Examples and claims). Since phosphatidylcholine can form a metal salt when inorganic salts are present, it is deemed that instant claims with specific ratios are included in Ueda.

*Claim Rejections - 35 U.S.C. § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 10, 13, 14, 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 354 442 cited above.

EP does not teach all of the claimed active agents. However, since EP teaches generic 'pharmaceutically active agent' is would have been obvious to one of ordinary skill in the art to use any active agent in EP's teachings with a reasonable expectation of success. Although EP teaches magnesium stearate, it does not teach that the salt of stearic acid to be a calcium salt. It would appear that Megalac recited in claim 20 is calcium salt of long chain fatty acids. In the absence of showing the criticality it is deemed to prepare any salt of stearic acid including calcium salts with the expectation of obtaining at least similar results.

14. Claim 10, 13-15, 17-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatalo (5,108,756) cited above.

Curatalo does not teach amino acids as the active agents. Curatalo also does not teach specific antibiotics. However, in view of Curatalo's generic teachings, it would have been obvious to one of ordinary skill in the art to use any active agent or specific antibiotics in Curatalo's teachings with a reasonable expectation of success. It would appear that Megalac recited in claim 20 is calcium salt of long chain fatty acids. In the absence of showing the criticality it is deemed to prepare any salt of stearic acid or other fatty acids including calcium salts with the expectation of obtaining at least similar results.

Since as pointed out above, phosphatidylcholine (lecithin) can form a metal salt when inorganic salts are present, it is deemed that instant claims with specific ratios are included in Curatalo.

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda (5,227,166) or Curatalo (5,108,756) or EP cited above, in combination with Chalupa (5,004,728).

What is lacking in Ueda or Curatalo or EP is the specific teaching of the use of calcium salts of fatty acids (Megalac). Such a use however, would have been obvious to one of ordinary skill in the art since the reference of Chalupa shows that Megalac increases the milk production in ruminants when given along with somatotropin (note Examples, Examples 1 and 2 in particular). If the intended goal were to increase the production of milk, one of ordinary skill in the art would be motivated to include Megalac in the compositions of Ueda, Curatalo or EP with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.

Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK